

**510(k) Summary of Safety and Effectiveness      FEB 13 2009****Zargis Acoustic Cardioscan**

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Zargis Medical Corporation is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Zargis Medical chooses to submit a summary of information respecting safety and effectiveness.

**Trade Name:** Zargis Acoustic Cardioscan (ZAC)

**Common Name:** Heart Sound Analyzer

**Regulation Number:** 21 CFR 870.1875, 870.2390

**Classification Name:** Stethoscope, Electronic; Phonocardiograph

**Product Code:** DQD, DQC

**Regulatory Class:** Class II

**Submitter Information:** Zargis Medical Corporation  
2 Research Way, 1<sup>st</sup> Floor  
Princeton, NJ 08540  
Tel: 609.734.4747  
Fax: 609.228.5000

**Summary Prepared By:** John Kallassy  
CEO

**Date Prepared:** November 3, 2008

**Predicate Devices:** Zargis Acoustic Cardioscan, K031517, K042128, K060197  
AViTA Bluetooth Blood Pressure Monitor, K072137  
*CardioBelt*™ Electrode Belt, K063044  
Nonin Medical, Inc. Model 4100 Patient Oximeter Module, K043359

**Device Description:** The ZAC is an electronic auscultatory device intended to acquire, record, and analyze heart sounds.

The complete system is a CD comprising software and instructions for use with an included USB transceiver for connection with a PC and capable of wireless

communication with a Bluetooth-enabled electronic stethoscope.

**Intended Use:** The Zargis Acoustic Cardioscan, (ZAC), is an electronic auscultatory device, intended to provide support to the physician in the evaluation of patients' heart sounds.

The product acquires and records the acoustic signals of the heart and analyzes these signals. The analysis procedure will identify specific heart sounds that may be present. Identified sounds include S1, S2, and suspected murmurs. The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.

The interpretations of heart sounds offered by the Zargis Acoustic Cardioscan are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

**Substantial Equivalence:** The modified ZAC is similar in design/technological characteristics, indications for use, and performance characteristics to the currently cleared ZAC product and other medical devices capable of wireless transmission of physiological data through use of Bluetooth technology. In addition, non-clinical performance testing has been conducted to demonstrate the performance of the modified ZAC device and that it meets its intended use.

**Safety and Performance:** A comprehensive list of verification and validation testing was performed in accordance with Zargis' Design Control procedures.

Software verification of the modified components was performed at the module and system level. The integrated ZAC system was further evaluated to verify the graphic user interface software and the ZAC system as an integrated product.

Validation of the ZAC was performed to ensure that the ZAC device consistently fulfills its intended use and the needs of the user. A clinical software validation was performed to insure the performance of the enhanced software algorithm.

The Bluetooth transceiver complies with all relevant FCC requirements.

**Conclusion:** Based upon the indications for use, technological characteristics and safety and performance testing, the Zargis Acoustic Cardioscan (ZAC) has been shown to be substantially equivalent to the currently cleared predicate devices under the Federal Food, Drug, and Cosmetic Act.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 13 2009

Zargis Medical Corp.  
c/o Mr. John Kallassy, CEO  
2 Research Way, 1<sup>st</sup> floor  
Princeton, NJ 08540

Re: K083309  
Trade/Device Name: Zargis Acoustic Cardioscan  
Regulation Number: 21 CFR 870.1875  
Regulation Name: Electronic Stethoscope  
Regulatory Class: Class II  
Product Code: DQD, DQC  
Dated: January 13, 2009  
Received: January 14, 2009

Dear Mr. Kallassy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

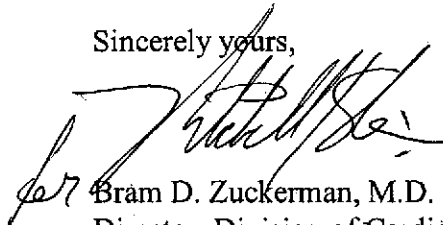
Page 2 – Mr. John Kallassy

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director, Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATION FOR USE

510(k) Number (if known): Not Assigned

Device Name: Zargis Acoustic Cardioscan

### Indications for Use:

*The Zargis Acoustic Cardioscan, (ZAC) is an electronic auscultatory device, intended to provide support to the physician in the evaluation of heart sounds in patients.*

*The product will acquire and record the acoustic signals of the heart and analyze these signals. The analysis procedure will identify specific heart sounds that may be present. Identified sounds include S1, S2, and suspected murmurs.*

*The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.*

*The interpretations of heart sounds offered by the Zargis Acoustic Cardioscan are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.*

Prescription Use: X

AND/OR

Over-The Counter Use:

(Per 21 CFR 801 Subpart D).....  
Subpart C)

(Per 21 CFR 801

(PLEASE DO NOT WRITE BELOW THIS LINE –  
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off) 2/3/09  
Division of Cardiovascular Devices

510(k) Number K083309